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(71)(72) Applicant and Inventor: WALKER, Rohan, Charles, Wilson [AU/AU]; 268 Richardson Street, Middle Park, VIC 3206 (AU).

(74) Agent: CHRISTIANSEN, John; Sandercock, Smith & Beadle, 207 Riversdale Road, P.O. Box 410, Hawthorn, VIC 3122 (AU).

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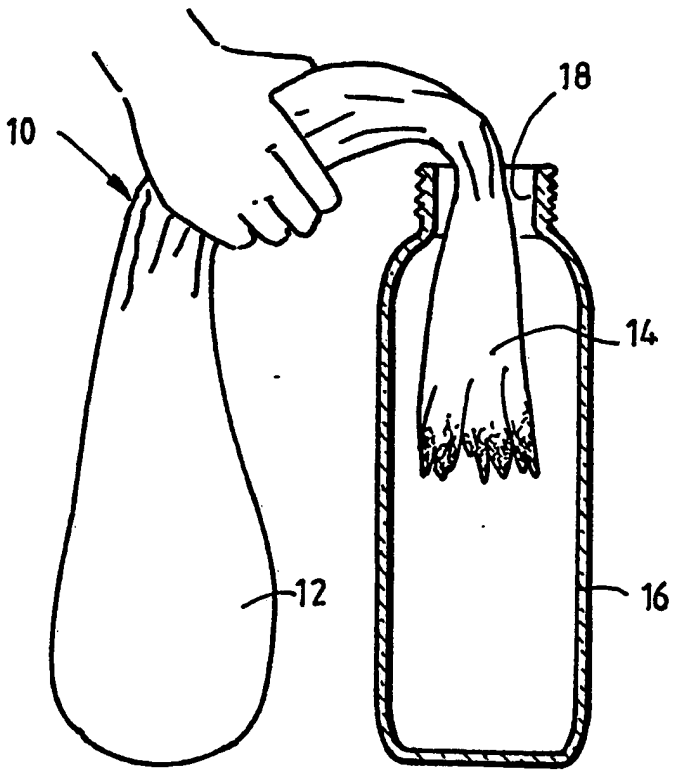
(54) Title: DISPOSABLE INSERTS FOR NURSING BOTTLES

(57) Abstract

A system for feeding infants with an artificial formula includes the supply of a formula (20) into a bag (10) under sterile conditions. The bag (10) is not completely filled with formula (20), the formula (20) occupying one portion (12) with another portion (14) being collapsed as a result of withdrawal of air therefrom. The bag (10) is sealed. In use, the collapsed portion (14) of a bag (10) is inserted into a nursing bottle (16) and the formula (20) caused to flow into the collapsed portion (14) located within the bottle (16). The former filled portion (12) is removed to provide an opening to the formula (20) in the bag (10), and the free end is located between a cap (26) holding a teat (28) and the neck (18) of the bottle (16). The formula (20) may have an increased initial vitamin content to allow for loss of vitamins during storage.



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DISPOSABLE INSERTS FOR NURSING BOTTLES

This invention relates to the nursing of infants.

For the first six months of a baby's life, its sole source of nourishment is milk. This can be:

- breast milk exclusively;
- breast milk complimented with an artificial formula; or
- an artificial formula exclusively;

After six months, other foods may be introduced, but milk still forms a major part of a child's diet for at least a further year.

The incidence of breastfeeding of infants in the State of Victoria, Australia, showed a dramatic drop between 1950 to 1970 but since then has been climbing steadily due to:

- the active encouragement of breastfeeding in hospitals;
- literature supplied to mothers promoting breastfeeding; and
- the efforts of such organisations as the Nursing Mothers' Association of Australia.

Where an infant in the sub-six months of age group is not completely breastfed, it is generally considered to be essential that it be fed on an appropriate commercial infant formula. These formulae are scientifically designed to resemble human milk as closely as technology will permit, and stringent standards have been prescribed for their manufacture.

Such formulae are dispensed to infants in nursing bottles. Conventional nursing bottles have a glass or plastic body portion, and a closure in the form of a screw-threaded cap into which a teat is fitted.

All literature on infant feeding stresses the need for sterility in the ingredients and equipment used for making up an artificial feed, whether it be a proprietary formula or ordinary milk.

Two methods are normally used to sterilise bottles and teats. The equipment can either be immersed in a chemical sterilising solution for one hour, or may alternatively be

placed in a suitable container, covered with water, brought to the boil and allowed to boil continuously in the water for ten minutes and then cooled. Great care must then be taken to ensure that all sterilised objects remain sterile.

Instructions supplied with all dried or concentrated infant formulae require the water which is to be added to reconstitute the formula to be boiled for at least ten minutes. The water will then take an hour or so to cool to body temperature. The powder or concentrate itself is kept in a sterile container which is usually fitted with a plastic lid which must itself be kept sterile. The contents are removed with a scoop which should also be sterilised and dried before use.

Since milk is a perfect medium for the growth of bacteria, prepared feeds are required to be kept under refrigeration.

Before being fed to the baby the feeds needs to be heated to bring it to at least room temperature and, if preferred, to body temperature. This can take several minutes during which time the parent is usually listening to a crying baby.

Thus, conventional artificial formulae feeding arrangements have disadvantages compared to breastfeeding. Breast milk is sterile, it requires no preparation, it has no storage problems, it does not need to be warmed before feeding is able to commence, it contains all vitamins, minerals and nutritional value required, and it is readily available.

Despite the foregoing problems artificial feeding does have distinct advantages

(a) Feeding duties can be shared

- the mother does not have to wake up for each night feed;

- the mother does not have to take the baby with her to work, to a social function or elsewhere where breastfeeding may not be practicable;

- the child can be left with a baby sitter to give the mother more freedom.

(b) The moth r knows precisely how much the baby takes in each feed.

(c) Some mothers choose not to breastfeed

- some women find it distasteful or messy;

- some women are unable to breastfeed or have difficulty breastfeeding because of some physical problem.

Thus, a feeding system which can eliminate or minimise the problems of artificial feeding will obviously benefit a great many people. Some efforts have been made to provide improved feeding arrangements, but these have not been successful.

In addition, most babies suffer from colic. In the case of bottle-fed babies this is occasionally caused or contributed to by the baby sucking against the vacuum in the feeding bottle.

To cope with this problem manufacturers recommend that the plastic closure on a nursing bottle that holds the teat should be left slightly untightened so as to admit air into the bottle as the baby sucks. In practice, however this system does not always work well and milk often leaks from the cap of the bottle during feeding.

A number of manufacturers have produced bottles specifically designed to overcome this problem but they are expensive and inconvenient to use. For example, Australian patent application no. 77971/75 to Hammer proposes the use of flexible bags for containing nursing liquids, to be used within a particular outer structure, but such an arrangement is costly, in that all the elements of the arrangement must be purchased to replace existing bottles.

US-A-3,762,542 to Grimes discloses the use of presterilised bags for insertion into a conventional 'nurser'. However, with such a system there is still scope for contamination of the formula dispensed into the bag.

It is an object of this invention to provide an improved system for feeding infants with artificial feeding formula.

The invention provides an infants' feeding system including a bag (10) containing a feeding formula (20) said

bag (10) having been filled in sterile conditions, said filled bag (10) having only a first portion (12) thereof occupied by said formula (20), a second portion (14) of which is collapsed due to the withdrawal of air therefrom, said second portion being capable of being inserted into a rigid container (16) such that the formula (20) may be caused to flow into said second portion (14) located within said container (16).

The invention also provides a method of producing a flexible container containing infants' formula (20), including the steps of partially filling an open-ended flexible container, partially filling said container with infants' formula (20), evacuating air from the remainder of said container to provide a collapsed portion thereof, and sealing said open end.

The invention further provides a sealed bag (10) containing infants' formula (20) and including a collapsed portion (14) for insertion into a container (16).

An embodiment of the invention will be described in detail hereinafter, with reference to the accompanying drawings, in which:-

Figure 1 is a perspective view of a bag filled with infant feeding formula;

Figure 2 is an elevation of a nursing bottle into which one end of the bag of Figure 1 is being located;

Figure 3 is an elevation of the nursing bottle of Figure 2 showing the liquid in the bag being transferred to the portion of the bag located in the bottle;

Figure 4 is an elevation of the bottle and bag of Figure 3, showing the bag about to be cut; and

Figure 5 is an elevation of a nursing bottle ready for use.

In the embodiment of the invention an artificial infants' feeding formula is prepared in sterile conditions and is packed in a disposable bag 10 (Figure 1) which preferably has the dimensions 180mm (circumference) by 330mm (length).

It is considered that as most plastics materials are

highly permeable to oxygen they would be unsuitable for use in forming a bag 10 because over the anticipated shelf life of the formula contained therein, the vitamin content, particularly of vitamin C and folic acid, would drop dramatically.

In order to compensate for this loss by boosting the vitamin content before manufacture so as to arrive at an acceptable vitamin content at the end of the contemplated shelf life, the result would be an unacceptably high vitamin level at the start of the shelf life period. The solution is to use a plastic material with a minimum permeability. Special plastic laminates are manufactured for this purpose and are used with the Intasept (referred to hereinafter) and other systems. It is also possible for such a laminate to be produced in a tubular form by an extrusion or other process.

Referring to Figure 1, a single feed, that is, a predetermined volume of liquid formula, is packed into each bag 10 in sterile conditions using a UHT (ultra high temperature) process which is used by the produce dairy products having long shelf life at ambient temperatures.

The manufacturing process involves -

1. Mixing the formula;
2. Sterilising the mixed formula;
3. Packing the mixed formula into bags 10;
4. Packing the bags 10 into boxes

Steps 1 and 4 will require a relatively simple plant. Step 2 will require the use of a UHT sterilising machine adjusted to the requirements of the product.

The greatest risk of contamination arises when the product leaves the UHT sterilising machine and enters the plastic bag 10. At this stage, assuming that the machine has been correctly adjusted and operated, the product should be sterile. The critical component is therefore the packing machine.

Because the product is intended for babies a high degree of reliability in the manufacturing process is essential. A one-in-five thousand failure rate, although

possibly acceptable for UHT household milk, is not good enough. Either an aseptic packaging machine will be required for this particular application or alternatively, an existing machine with a high degree of reliability will need to be adapted.

The "Intasept" aseptic 2-30 litre filler manufactured by Wrightcel Limited is claimed to have a high degree of reliability and can be very easily adapted to this application with a minimum of cost.

The feed only occupies bottom section 12 of bag 10 and the remainder 14 of the bag has the air evacuated therefrom. Immediately after filling, the bag is sealed by conventional means to prevent any contamination.

The size of the feed packaged in this way would depend upon the age of the baby. It is suggested that the feeds would be marketed in a 150 millilitre size and a 250 millilitre size. The size of the bag 10, however, would preferably remain the same.

The filled bags are then packed in cardboard boxes or the like, containing a given number of feeds to each box.

Being sterile, these boxes of infant feeds could be sold "off the supermarket shelf" and would not require refrigeration. The anticipated shelf life is three months.

Figures 2 to 5 inclusive demonstrate the manner in which a feed is prepared after a filed bag 10 has been purchased by a parent.

The parent would obtain a filled bag 10 from a cupboard or other storage area.

As shown in Figure 1, the parent would then insert the collapsed end 14 of bag 10 into the open end 18 of a conventional nursing bottle 16. The parent then raises filled end 12 of the bag 10 (Figure 3) so that the infants' formula 20 flows in the direction of the arrows to end 14, which is located in bottle 16. The formula 20 is then within the bottle 16, but is separated therefrom by the material from which bag 10 is formed.

The former bottom portion 12 of the bag 10 which now protrudes above the neck 18 of the bottle 16 is now

substantially devoid of milk, and the outer portion of this is cut off with scissors or the like 22 to form an open-ended bag leaving, preferably at least sixty millimitres of the bag 10 protruding above the neck of the bottle (Figure 3).

The sides 24 of this open bag are now pulled down over the outside of the neck 18 of the bottle 16 (Figure 4) and a cap 26 holding a teat 28 is screwed onto the neck 18 of bottle 16, clamping the sides 24 between it and the neck 18. Thus, the bottle 16 is now ready for the formula to be dispensed to the infant.

It will be observed that the system of this invention has the following advantages:-

(a) The bottle does not require sterilisation, because no part of the milk touches it.

(b) The feed does not need to be heated since it is already at room temperature. If it is desired to bring the feed to blood temperature, only minimal heating is required.

(c) An unlimited number of feeds can be taken in the car, camping, on picnics or elsewhere where sterile facilities for the preparation of feeds are not available. All that is required is a jar or other small container of sterilising solution for the teat and screw on cap.

(d) The mother can be certain that the feed is completely sterile because there is no possibility of contamination.

(e) The system fits all commonly used feeding bottles without any modification required.

(f) If a hole is made in the feeding bottle, the bag 10 will collapse like the inside of a wine cask as the baby feeds. Since the baby does not have to suck against a vacuum, the chances of colic are diminished.

It is considered that the formula packed in bags 10 will need to be initially boosted with vitamins, particularly vitamins A, C and folic acid, which will be lost:

- due to the heat of the UHT process;
- due to oxygen contamination during storage; or

- du t the effect of light. Losses du to light can be minimised by packing the bags into an appropriate box. Oxygen contamination can be minimised by using an appropriate plastic laminate for the bags, as discussed hereinbefore.

The claims form part of the disclosure of this specification.

CLAIMS:

1. An infants' feeding system including a bag (10) containing a feeding formula (20) said bag (10) having been filled in sterile conditions, said filled bag (10) having only a first portion (12) thereof occupied by said formula (20), a second portion (14) of which is collapsed due to the withdrawal of air therefrom, said second portion being capable of being inserted into a rigid container (16) such that the formula (20) may be caused to flow into said second portion (14) located within said container (16).

2. An infants' feeding system according to claim 1, wherein said container (16) is a nursing bottle (16).

3. An infants' feeding system according to claim 1 or claim 2, wherein said first portion (12) is removed to provide access to said formula (20) when said second portion (14) is filled and located within said container (16) and wherein said open end may be trapped between a neck (18) of said container and dispensing apparatus (26, 28) for said formula (20).

4. An infants' feeding system according to claim 3, wherein said dispensing apparatus (26,28) includes a teat (28).

5. An infants' feeding system according to any preceding claim, wherein said formula (20) has an initial boosted vitamin content.

6. A method of producing a flexible container containing infants' formula (20), including the steps of partially filling an open-ended flexible container, partially filling said container with infants' formula (20), evacuating air from the remainder of said container to provide a collapsed portion thereof, and sealing said open end.

7. A method according to claim 6, wherein said open-ended flexible container is a substantially tubular member having one open end and being formed from a minimum-permeability plastics laminate material.

8. A sealed, st rile bag (10) containing infants' formula (20), when produced by the method of claim 6 or 7.

9. A sealed sterile bag (10) substantially as herein describ d with reference to the accompanying drawings.

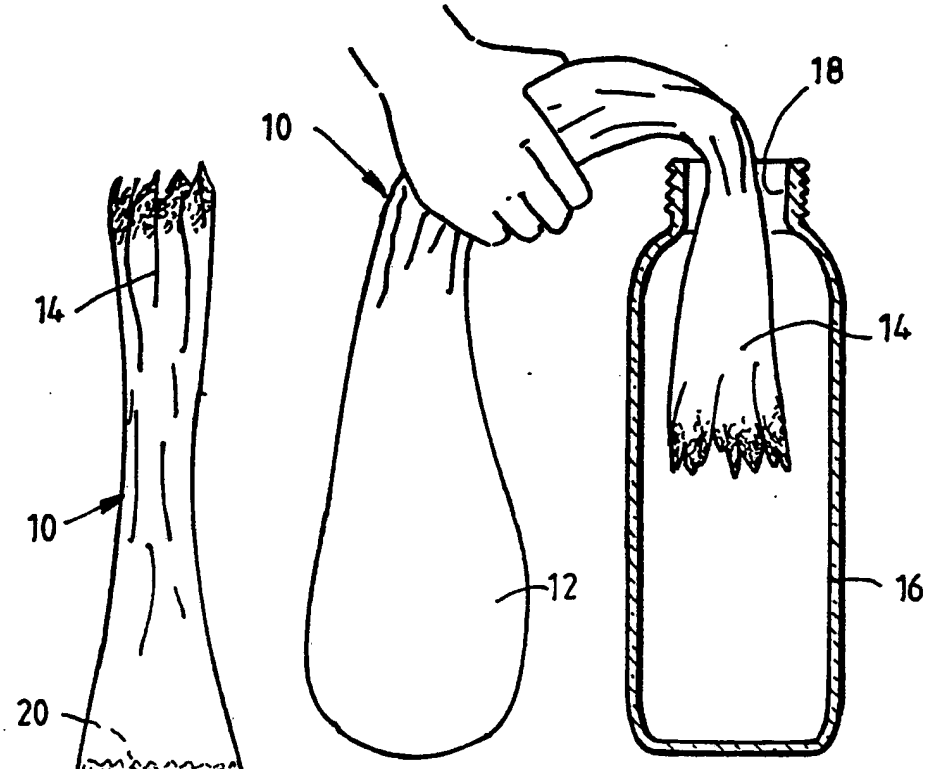

FIG. 2.

FIG. 1.

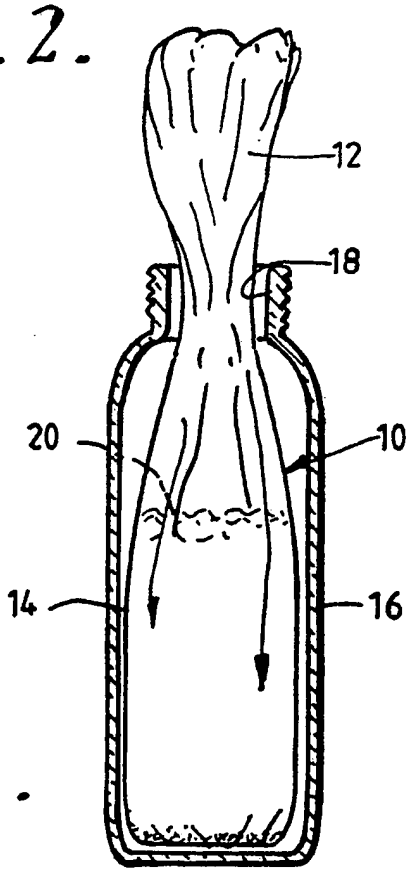

FIG. 3.

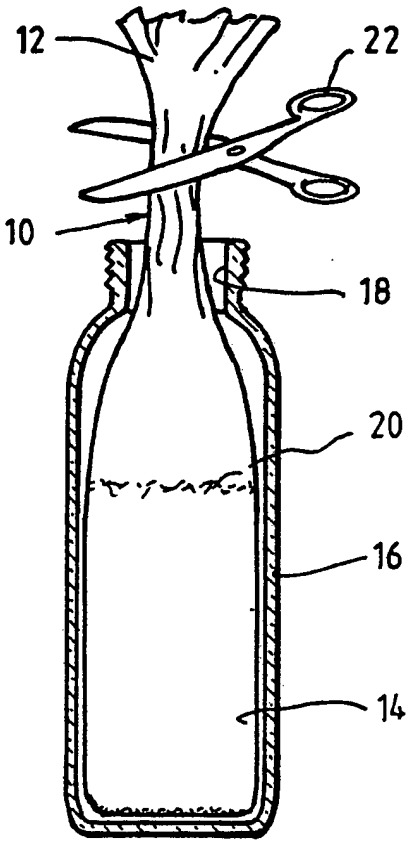

FIG. 4.

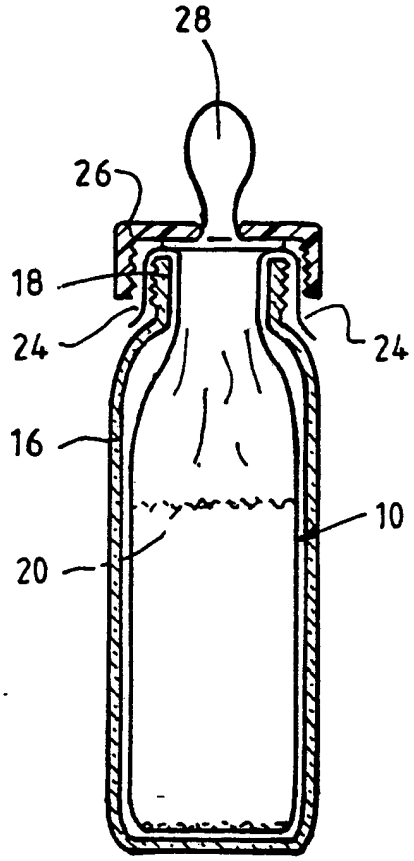

FIG. 5.

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00198

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61J 9/00, 9/08 // A23C 3/023, B65B 29/00

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
IPC	A61J 9/00, 9/08, A23C 3/023

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	AU,A, 65873/65 (McKENNA) 4 May 1967 (04.05.67) (See p.5, l.22 - p.8, l.23; Claims; Drawings)	
A	AU,B, 246/66 (CONTINENTAL CAN CO., INC.) 13 July 1969 (13.07.69)	
A	AU,A, 17756/70 (PERLMAN) 10 February 1972 (10.02.72) (See Claims 1,10)	
A	US,A, 3507666(CHENEY et al) 21 April 1970 (21.04.70)	
A	US,A, 3593871 (BUNDY) 20 July 1971 (20.07.71)	
A	AU,A, 77971/75 (HAMMER) 12 August 1976 (12.08.76) (See p.5, l.32 - p.8, l.32)	
A	AU,A, 25112/77 (GRACE) 16 November 1978 (16.11.78)	
A	EP,A, 129326 (FRES-CO SYSTEM USA, INC.) 27 December 1984 (27.12.84)	
A	WO,A, 85/04571 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	
A	WO,A, 85/04574 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	
A	WO,A, 85/04575 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22 September 1987 (22.09.87)	(09.10.87) 9 OCTOBER 1987
International Searching Authority	**Signature of Authorized Officer**
Australian Patent Office	A.HENDRICKSON

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL APPLICATION NO. PCT/AU 87/00198

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members			
AU 17756/70	US 3578239	US 3716369		
EP 129326	US 4518087	US 4576285	US 4667453	
WO 8504571	EP 179846	ZA 8502695		
WO 8504574	ZA 8502699			
WO 8504575	EP 176569	ZA 8502700		

END OF ANNEX